

**REMARKS**

Applicant would like to thank the Examiner for the detailed Official Action provided. Applicant would also like to thank Examiner Bosworth and her Supervisor Kevin Sirmons for granting Applicant's Representative, Steven Pollicoff (Reg. No. 60,311), the telephonic interview that was conducted on June 4, 2009.

During the interview, Applicant's Representative discussed the differences between the claim limitations recited in independent claims 1 and 4, and the applied prior art references. More specifically, Applicant's Representative pointed out the clear differences between the seal projections, as generally recited in independent claims 1 and 4, and the o-ring 82 and the "portion A" of SULLIVAN et al. (U.S. PGPUB 2002/0092521, now U.S. Pat. No. 6,929,005) that the Examiner alleges corresponds to the claimed seal projections. Proposed claim amendments were discussed, but unfortunately no agreement was reached regarding the pending claims. However, Applicant appreciates the professional and cooperative nature in which Examiner Bosworth and her Supervisor conducted the interview.

Upon entry of the present response, independent claims 1, 3, 4 and 6 will have been amended. The amendments to claims 3 and 6 will have been made merely for cosmetic purposes (*i.e.*, for purposes of consistency and clarity), and should not be considered to have been made for purposes related to the patentability of the present application. No new matter will have been introduced by the above-made amendments. Claims 1-6 are pending for consideration by the Examiner. Applicant respectfully requests reconsideration and withdrawal of the outstanding rejections of the claims pending in the present application. Such action is respectfully requested and is now believed to be appropriate.

**Obviousness Rejections Under 35 U.S.C. §103**

The Examiner has rejected claims 1-4 and 6 as being unpatentable under 35 U.S.C. §103(a) over COCOZZA (U.S. Pat. No. 4,013,075) in view of SULLIVAN et al. (U.S. PG PUB 2002/0092521, now U.S. Pat. No. 6,929,005), and claim 5 as being unpatentable over COCOZZA in view of SULLIVAN, and further in view of OHKI et al. (U.S. Pat. No. 6,341,605). Applicant respectfully traverses the obviousness rejections and requests withdrawal of the rejections in view of the following remarks.

For an obviousness rejection under §103(a) to be proper, the cited references must indicate that each limitation is shown or the Examiner must provide at least a clear articulated reason for rendering the claimed invention obvious. In this regard, it is respectfully asserted that COCOZZA, either alone or in any proper combination with SULLIVAN, fails to disclose or render obvious the combination of features as recited in at least amended independent claims 1 and 4.

Independent claims 1 and 4, as amended, each generally recite a device to deliver a powdery medicine contained in a capsule to a nasal cavity. The device includes, *inter alia*, a main body having a loading space and configured to hold the capsule between a connection port on a side of a nozzle and a connection port on a side of a pump, a capsule holder that holds the capsule, is slidably movable from the main body, and configured to position the capsule in a loading position in the loading space between the connection ports. The device also includes a cutter that partially cuts off both ends of the capsule that moves forward to the loading position while being held by the capsule holder, the cutter including a pair of blades secured in parallel with each other at opposite sides of the loading space between the connection ports, and each blade having a blade tip directed in a direction opposing the advancing direction of the capsule

holder. Peripheral portions of the main body define at least a portion of both of the connection ports and are formed as seal projections that project from surfaces of the blades toward the loading space, and the distance between the seal projections is shorter than the length of the capsule after cutting off both ends by the cutter, so that both ends of the capsule loaded between them are pressed by both seal projections.

In setting forth the rejection of independent claims 1 and 4, the Examiner asserts that COCOZZA discloses the combination of features as generally recited except for 1) disclosing that the peripheral portions of both of the connection ports are formed as seal projections that project from surfaces of the blades toward the loading space, and 2) that the distance between the seal projections is shorter than the length of the capsule after cutting off both ends by the cutter, so that both ends of the capsule loaded between them is pressed by both seal projections. The Examiner, however, introduces SULLIVAN and asserts that SULLIVAN discloses a similar delivery device having an o-ring and a "portion A" corresponding to the seal projections, as generally recited. The Examiner then concluded that it would have been obvious to one having ordinary skill in the art to modify COCOZZA to include the o-ring and the "portion A" to project from the blades of COCOZZA for the purpose of assuring a sealed relation between the capsule and the device.

Applicant agrees that COCOZZA at least fails to disclose 1) that the peripheral portions of both of the connection ports are formed as seal projections that project from surfaces of the blades toward the loading space, and 2) that the distance between the seal projections is shorter than the length of the capsule after cutting off both ends by the cutter, so that both ends of the capsule loaded between them is pressed by both seal projections. However, Applicant asserts that SULLIVAN fails to cure the deficiencies of COCOZZA, and further asserts that

COCOZZA, either alone or in any proper combination with SULLIVAN, fails to render obvious at least the seal projections, as generally recited in amended independent claims 1 and 4.

In this regard, SULLIVAN merely discloses a medicament delivery device that includes an inlet housing member 54 that is *screw-fitted* to an outlet housing member 56. The inlet housing member 54 and the outlet housing member 56 define a cylindrical chamber 62 to retain a medicament cartridge 20. During assembly of the delivery device, an o-ring 82 is provided in the chamber 62 at a first end of the inlet housing member 54 (before insertion of the cartridge 20) to assure a sealed relation between the cartridge 20 and the chamber 62 when outlet housing member 56 is *screw-fitted* to the inlet housing member 54. *See e.g.*, FIG. 4; *see also* col. 8, line 63 – col. 9, line 8.

SULLIVAN further discloses that the cartridge 20 is generally cylindrical and includes flat ends, each flat end including a polymeric membrane 30, 32 to seal medicament within the cartridge 20. The polymeric membranes 30, 32 have a burst pressure so as to allow air (or fluid) to mix with the medicament within the cartridge before delivery to a user. *See* col. 6, lines 26-30. Applicant asserts that SULLIVAN fails to disclose that the inlet housing member 54, including the chamber 62, is slidably movable, and that the delivery device includes a cutter including a pair of blades.

In the Official Action, the Examiner asserts that an inlet tube 58 and an outlet tube 64 of SULLIVAN generally correspond to the alleged connection ports 35 and 37 of COCOZZA, and that the o-ring 82 and the “portion A” (defining sides of the outlet housing member 56, as shown by the Examiner in the Official Action of March 31, 2009, at page 5) correspond to the seal projections, as generally recited in independent claims 1 and 4.

However, contrary to the Examiner's assertions, Applicant asserts that the o-ring 82 is not a peripheral portion of the inlet tube 58 formed as a seal projection that projects from a surface of a blade. Rather, the o-ring 82 is merely a single seal member, separate from the inlet tube 58, which is provided within the inlet housing member 54 and contacts a beveled side edge of the cartridge 20. *See e.g.*, FIG. 4. Further, the o-ring 82 is not a peripheral portion of the inlet housing member 54 that defines at least a portion of the inlet tube 58, and formed as seal projection that projects from a blades towards chamber 62. Put another way, the o-ring 82 does not project from a blade and only functions to seal the cartridge 20 in the inlet housing member 54 when the outlet housing member 56 is *screw-threaded* to the inlet housing member 54. *See e.g.*, FIG. 4; *see also* col. 8, line 63 – col. 9, line 8. Thus, for at least these reasons Applicant asserts that the o-ring 82 cannot reasonably be considered to be a seal projection, as generally recited in amended independent claims 1 and 4.

Similarly, Applicant asserts that the “portion A” cannot reasonably be considered a seal projection, as generally recited in amended independent claims 1 and 4. More specifically, and contrary to the Examiner's assertions, “portion A” (as shown in the Official Action of March 31, 2009, at page 5) is not a peripheral portion of the outlet housing member that defines at least a portion of the outlet tube 64, and formed as a seal projection that projects from a surface of a blade. Rather, the “portion A” merely defines a portion of the outlet housing member 56 that is configured to be *screw-fitted* to the inlet housing member 54 to seal the cartridge 20 for medicament delivery operations. Further, Applicant asserts that the “portion A” merely conforms to the outer side edge shape of the generally cylindrical cartridge 20 (and does not project from a blade) so as to secure the cartridge in a stationary position when the inlet housing member 54 and the outlet housing member 56 are *screw-fitted* together. This configuration

enables the polymeric membranes 30, 32 at the flat ends of the cartridge 20 to burst and allow the air/fluid medicament mixture of the cartridge to be dispensed to the user. *See e.g.*, FIGS. 4-5. Thus, for at least these reasons Applicant asserts that the “portion A” cannot reasonably be considered to be a seal projection, as generally recited in amended independent claims 1 and 4.

However, even if the o-ring 82 and the “portion A” could be considered to be seal projections, as generally recited, Applicant asserts that one having ordinary skill in the art would not look to modify the COCOZZA device with the o-ring 82 and the “portion A” of SULLIVAN for the purpose of assuring a sealed relation between the capsule and the device, as asserted by the Examiner.

In this regard, Applicant asserts that the Examiner has failed to articulate a clear reason for why one having ordinary skill in the art would modify the COCOZZA device to include the o-ring 82 of SULLIVAN at the alleged connection port 35 of COCOZZA and the “portion A” of the outlet housing member 56 of SULLIVAN at the alleged connection port 37 of COCOZZA.

Applicant asserts that the proposed modification would render the COCOZZA device unsatisfactory for its intended purpose, *i.e.*, pivotally loading and cutting the capsule for delivery to the user. That is, the configuration of the COCOZZA device is completely different than the configuration of the SULLIVAN device. If the COCOZZA device were modified as suggested by the Examiner, the o-ring 82 of SULLIVAN would likely be provided to contact the capsule before the capsule is cut so as to secure and seal the capsule in the bore 15 of COCOZZA. In this regard, the o-ring 82 would likely necessarily be placed at the lower end of the bore 15 so as to seal the capsule from the alleged connection port 35, as clearly shown in SULLIVAN. This configuration would likely prevent the capsule from being cut, which is

contrary to the intended purpose of COCOZZA. Thus, Applicant is unclear why one having ordinary skill in the art would make such a modification.

Similarly, Applicant asserts that if COCOZZA were modified to include the "portion A" of SULLIVAN, the "portion A" would likely be provided at the lower end of the alleged connection port 37 of COCOZZA so as to also secure the capsule in the bore 15 before the capsule is cut. However, to secure the capsule to the bore 15, in the manner suggested by the Examiner, COCOZZA would have to be further modified so that the outlet portion 32 of COCOZZA were *screw-fitted* to the capsule holder 12. However, if the outlet portion 32 were *screw-fitted* to the capsule holder 12 so that the capsule were secured by the o-ring 82 and the "portion A" before cutting, then the capsule holder 12 would be prevented from being pivotally rotatable in and out of the body 31, as taught by COCOZZA. In other words, if COCOZZA were modified as suggested by the Examiner, the blades 20 and 20', as configured, would likely be prevented from cutting the top and bottom portions of the capsule, at least because the COCOZZA device is designed to cut the capsule when the capsule holder is rotated into the body 31, *i.e.*, loaded into the body. If the COCOZZA device is modified to have the capsule loaded in a screw-fit manner, as disclosed in SULLIVAN, the COCOZZA device would fail to operate as intended. Thus, because the pivoting/cutting loading configuration of COCOZZA is completely different than the *screw-fitting*/bursting configuration of SULLIVAN, Applicant asserts that the resultant device would be inoperable for its intended purpose.

Applicant also asserts that SULLIVAN fails to disclose or render obvious that a distance between the o-ring 82 and the "portion A" is shorter than the length of the capsule after cutting off both ends by the cutter, so that both ends of the capsule loaded between them are pressed by both seal projections. First, it is clear that SULLIVAN does not disclose cutting the cartridge 20,

at least because the cartridge 20 is specifically designed to burst at polymeric membranes 30 and 32. However, even if the “bursting” could be considered as “cutting” the cartridge 20, the ends of the cartridge 20 are not pressed by both the o-ring 82 and the “portion A.” As clearly shown in the drawings, the flat ends (at references 30 and 32) extend past both the o-ring 82 and the “portion A,” and are not pressed by either the o-ring 82 or the “portion A.” At best, beveled side edges of the cartridge 20 are pressed by the o-ring 82 and the “portion A.” *See e.g.*, FIG. 4. Thus, for at least these additional reasons Applicant asserts that COCOZZA, either alone or in any proper combination with SULLIVAN, fails to disclose or render obvious the combination of features as generally recited in at least amended independent claims 1 and 4.

Further, Applicant asserts that rejected claims 2, 3, 5 and 6 are dependent, either directly or indirectly, from at least one of allowable independent claims 1 and 4, which are allowable for at least the reasons discussed *supra*. Thus, these dependent claims are also allowable for at least the reasons discussed *supra*. Further, claims 2, 3, 5 and 6 set forth further combinations of elements neither disclosed nor rendered obvious by any of the references of record. It is thus respectfully requested that the Examiner withdraw the rejections of claims 2, 3, 5 and 6 under 35 USC §103(a) as well.

Thus, for each of the above-noted reasons and certainly for all of the above-noted reasons, it is respectfully asserted that the Examiner's rejections are inappropriate and improper. Accordingly, Applicant respectfully requests reconsideration and withdrawal of each of the outstanding rejections together with an action indicating the allowability of all the claims pending in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.



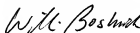
**SUMMARY AND CONCLUSION**

Applicant asserts that the present application is in condition for allowance, and respectfully requests an indication to that effect. Applicant has argued the allowability of the claims and pointed out deficiencies of the applied references. Accordingly, reconsideration of the outstanding Official Action and allowance of the present application and all the claims therein are respectfully requested and is now believed to be appropriate.

Applicants note that this amendment is being made to advance prosecution of the application to allowance, and should not be considered as surrendering equivalents of the territory between the claims prior to the present amendment and the amended claims. Further, no acquiescence as to the propriety of the Examiner's rejection is made by the present amendment. All other amendments to the claims which have been made in this amendment, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Tatsuo TSUTSUI

  
Bruce H. Bernstein  
Reg. No. 29,027

William S. Boshnick  
Reg. No. 44,550

June 15, 2009  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191